NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement, "As assayed by the method described in U. S. P. XII for Digitalis, each tablet has a potency of 1.25 U. S. P. Digitalis units," was false and misleading since the potency of the article as indicated by the method described in the Twelfth Revision of the United States Pharmacopoeia was materially in excess of 1.25 U. S. P. Digitalis Units; and, Section 502 (j), the article was dangerous to health when used in the dosage suggested by the statement quoted above, since, if prescribed by a physician in reliance upon such statement of potency, the patient would receive an excessive amount of a potent drug.

DISPOSITION: August 9, 1946. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUG REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

2002. Misbranding of penicillin sodium. U. S. v. 102 Vials of Penicillin Sodium. Default decree of condemnation. Product ordered delivered to public welfare institution. (F. D. C. No. 20248. Sample Nos. 14070–H, 14072–H, 14073–H.)

LIBEL FILED: June 12, 1946, Eastern District of Kentucky.

ALLEGED SHIPMENT: On or about February 8, 1946, by the Hale-Justis Drug Co., from Cincinnati, Ohio.

PRODUCT: 102 vials of *penicillin sodium* at Lexington, Ky. The product had not been certified in accordance with the requirements of the law.

LABEL, IN PART: "No. 732 Penicillin Sodium 100,000 Oxford Units (Mfd. by Heyden Chemical Corporation) * * * Supplied by Lakeside Laboratories Milwaukee, Wisconsin."

NATURE OF CHARGE: Section 502 (l), the article was a drug composed in whole or in part of a derivative of penicillin, and it was not from a batch with respect to which a certificate of release, issued pursuant to the regulations, was in effect.

DISPOSITION: August 9, 1946. No claimant having appeared, judgment of condemnation was entered and the product was ordered delivered to public welfare institutions, since the Food and Drug Administration had certified that the product was fit for use.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

2003. Misbranding of sulfathiazole tablets, sulfadiazine tablets, and nembutal capsules. U. S. v. I. James Hendelberg (Southeast Pharmacy). Plea of nolo contendere. Fine, $400. (F. D. C. No. 19538. Sample Nos. 2966–H to 2968–H, incl., 2971–H.)

INFORMATION FILED: April 19, 1946, District of Columbia, against I. James Hendelberg, trading as Southeast Pharmacy, Washington, D. C.

PRODUCT: *Sulfathiazole tablets* and *sulfadiazine tablets*, sulfa drugs; and *nembutal capsules* which contained pentobarbital, a derivative of barbituric acid, which has been designated as habit forming.

NATURE OF CHARGE: That between the approximate dates of December 27, 1945, and January 17, 1946, while the articles were in interstate commerce, the defendant repacked a quantity of the various articles in unlabeled envelopes and boxes.

The information further charged that the acts of the defendant resulted in the misbranding of the articles in the following respects: Section 502 (b) (1) and (2), the articles failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; Section 502 (e), they were not designated solely by names recognized in an official compendium, and they failed to bear labels declaring the common or usual names of the articles; Section 502 (f) (1), they were without labels bearing adequate directions for use; and, Section 502 (f) (2), they were without labels bearing such adequate warnings against use in those pathological conditions or by children where their use may be

dangerous to health, or against unsafe dosage or methods or duration of administration or applications, in such manner and form as are necessary for the protection of users.

Further misbranding, *nembutal* (pentobarbital sodium), Section 502 (e), the article failed to bear a label containing the name and quantity or proportion of such substance or derivative and, in juxtaposition therewith, a statement "Warning—may be habit forming."

DISPOSITION: April 22, 1946. The defendant having entered a plea of nolo contendere, the court imposed the fine of $100 on each count, a total fine of $400.

2004. Misbranding of Nu Pep Tonic Tablets. U. S. v. David Klebanoff (Dake Pharmacal Company). Plea of nolo contendere. Fine, $250. (F. D. C. No. 16605. Sample Nos. 22518–H, 29023–H.)

INFORMATION FILED: January 29, 1946, Eastern District of Pennsylvania, against David Klebanoff, trading under the firm name of Dake Pharmacal Company, Philadelphia, Pa.

ALLEGED SHIPMENT: On or about December 1 and 10, 1944, from the State of Pennsylvania into the States of Illinois and California.

LABEL, IN PART: "Nu Pep Tonic Tablets."

NATURE OF CHARGE: Misbranding, Section 502 (a), the name "Nu Pep" was false and misleading since the article, when used as directed, would not produce new pep. Further misbranding, Section 502 (a), the labeling of the article was misleading in that it failed to reveal the fact that orchic substance, prostate glands, powdered extract damiana, and powdered extract gentian and avenin were not active ingredients, which fact was material in the light of the following representations displayed upon the box containing the article: "Contents of Each Tablet Strychnine Sulphate 1/80 gr. Yohimbine Hydrochloride 1/10 gr. Zinc Phosphide 1/10 gr. Orchic Substance 1/2 gr. Prostate Glands 1 gr. Powd. Ext. Damiana 1 gr. Powd. Ext. Gentian 1 gr. Avenin 1 gr."

Further misbranding, Section 502 (f) (2), the label of the article failed to bear such adequate warnings against use in those pathological conditions where its use may be dangerous to health, or against unsafe dosage and duration of administration, in such manner and form, as are necessary for the protection of users. The article contained strychnine, and its labeling failed to bear a warning that the use for elderly persons of a product containing strychnine may be especially dangerous and that frequent and continued use of a product containing strychnine should be avoided, since frequent or continued use of the product may result in the administration of an amount of strychnine which would be unsafe.

DISPOSITION: June 5, 1946. The defendant having entered a plea of nolo contendere, the court imposed a fine of $250.

2005. Misbranding of drug tablets. U. S. v. 70,600 Tablets and 52,000 Tablets. Default decree of condemnation and destruction. (F. D. C. No. 21623. Sample Nos. 5340–H, 5341–H.)

LIBEL FILED: On or about November 12, 1946, District of New Jersey.

ALLEGED SHIPMENT: On or about July 19 and September 3, 1945, by Strong Cobb & Co., Inc., from Cleveland, Ohio.

PRODUCT: 70,600 *tablets* and 52,000 *tablets* at Cologne, N. J. Analysis showed that the 70,600-tablet lot contained bismuth carbonate, magnesium sulfate, charcoal, and salol; and that the 52,000-tablet lot contained copper sulfate, magnesium sulfate, and potassium permanganate. The *tablets* were shipped in bulk containers, and no written agreement as to the labeling of the *tablets* existed between the consignee and the shipper.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of both lots of the tablets failed to bear adequate directions for use; and, Section 502 (e) (2), the label of the 52,000-tablet lot failed to bear the common or usual name of each active ingredient.

DISPOSITION: December 9, 1946. No claimant having appeared, judgment of condemnation was entered and the tablets were ordered destroyed.